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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,599	02/02/2001	John Craig Smith	P 276655 LDSG/Z70655/US	6247

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EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	8

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/773,599	Applicant(s) SMITH, JOHN CRAIG
	Examiner Juliet Einsmann	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 3, 4, 5, 7, and 8, drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis, classified in class 435, subclass 6.

II. Claims 1, 6, 7, and 9, drawn to a method for the diagnosis of a polymorphism using protein analysis, classified in class 435, subclass 7.1.

III. Claims 10-15, drawn to isolated nucleic acids, classified in class 536, subclass 23.1.

IV. Claim 13, 16 drawn to methods of treating a human in need of treatment, classified in class 424, subclass 94.1.

V. Claim 17, drawn to methods of treating a human in need of treatment, classified in class 424, subclass 94.1.

VI. Claims 18 and 19, drawn to a method to prepare a medicament and a pharmaceutical pack, classified in class 424, for example.

VII. Claim 20-22, drawn to a computer readable medium comprising nucleic acids, classified in class 702, subclass 19.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is claims or utilizes one of the distinct polymorphism that are recited within the claims. For example, group I above encompasses eight different inventions, that is, methods for detecting each of the eight different nucleic acid

polymorphisms, and group II encompasses two different inventions, that is, methods for detecting each of the two polypeptide polymorphisms recited. For the elected group (of groups I-VII), applicants must further elect single polymorphism for examination in the appropriate product or method claim. Applicant should identify the polymorphism being elected as well as any particular SEQ ID NO's related to the polymorphism, as appropriate. For example, if applicant elects group I, applicant should further elect one of the nucleotide polymorphisms for examination. Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicant is advised that examination will be restricted to only the elected SNP and SEQ ID NO. and this restriction should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

2. Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic

variations which have different diagnostic and therapeutic implications. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

3. Inventions I, II, IV, V and VI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods with different goals, distinct method steps and requiring different reagents and different techniques. The methods of invention I are drawn to the detection of nucleic acid polymorphisms, and require the use of nucleic acid analysis techniques, such a DNA sequencing or nucleic acid hybridization assays. The methods of invention II are drawn to the detection of polymorphisms in amino acid sequences, and require the use of protein analysis techniques such as ELISA or polypeptide sequencing. The methods of invention IV have the goal of treating humans and require a step of administering a drug to a human in need of treatment, and require a diagnostic step utilizing nucleic acid techniques. The method of invention V also have the goal of treating humans, require a step of administering a drug to a human in need of treatment, but differ from the methods of invention IV because they require a diagnostic step that utilizes protein analysis techniques. The methods of group VI are directed towards the preparation of medicaments and would require the steps and reagents necessary to prepare the particular medicament for the treatment of disease.

4. Inventions I and III and inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions III can each be used in separate methods from those instantly disclosed. The nucleic acids of invention III can be used in other methods, such as to express the encoded polypeptide, for nucleic acid purification assays and for aptamer assays. The computer readable medium can be used in other methods such as for sequencing methods or capture assays for the detection of target molecules.

5. Invention II is unrelated to the products of group III, VI and VII. The products of invention III are unrelated to the methods of inventions IV, V, and VI. The methods of invention IV are unrelated to the products of inventions VI, VIII and IX. Invention V is unrelated to inventions VI and VII. Invention VI is unrelated to invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the groupings represents unrelated inventions because the products are not disclosed for use in the particular methods provided. For example, the pharmaceutical pack of group V is not disclosed for use in the methods for diagnosing polymorphisms of group I. Likewise, the nucleic acids of group III are not disclosed for use in the methods for preparing medicaments of group V. In each case, the products and methods are not necessary for the practice of the unrelated inventions.

6. The products of groups III, VI, and VII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group III are composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix.

The medicament of group VI is a chemical compound designed to have bioaffecting activity for the treatment of disease. The computer readable medium is comprised of a silicone chip or a disk or some hard structure with nucleic acids attached or a memory storage device (such as a computer disk) that has sequence information. Furthermore, the products of Groups III, VI, and VII can be used in materially different processes, for example, the DNA of Group III can be used in hybridization assays, the computer readable medium of group VI can be used in sequencing reactions and methods to determine sequence identity and he pharmaceutical pack can be used to treat disease or conditions associated with the EP1-R gene. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups III, VI, and VII are patentably distinct from each other.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Juliet C Einsmann
Examiner
Art Unit 1655

May 7, 2002